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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) <div style="text-align: center;">20555/1203301-US3</div>	
	Application Number <div style="text-align: center;">10/084,380-Conf. #3496</div>	Filed <div style="text-align: center;">February 28, 2002</div>	
	First Named Inventor <div style="text-align: center;">Daniel G. Chain</div>		
	Art Unit <div style="text-align: center;">1649</div>	Examiner <div style="text-align: center;">G. S. Emch</div>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 60%;"> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>46,550</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> </div> <div style="width: 35%; text-align: center;"> <p>_____ /Mitchell Bernstein/ Signature</p> <p>_____ Mitchell Bernstein Typed or printed name</p> <p>_____ (212) 527-7700 Telephone number</p> <p>_____ February 19, 2009 Date</p> </div> </div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<input type="checkbox"/> *Total of <u>1</u> forms are submitted.			

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Daniel G. Chain

Application No.: 10/084,380

Confirmation No.: 3496

Filed: February 28, 2002

Art Unit: 1649

For: SPECIFIC ANTIBODIES TO AMYLOID BETA
PEPTIDE, PHARMACEUTICAL COMPO-
SITIONS AND METHODS OF USE THEREOF

Examiner: G. S. Emch

SUBMISSION TO ACCOMPANY PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. INTRODUCTION

This Submission sets forth the basis for Applicant's concurrently submitted pre-appeal brief request for review. Upon entry of an Amendment Under Rule 1.116 that was submitted on Dec. 11, 2008, claims 14, 19, 20, 25, 55, 56, 72, 75, 93-98 and 105-108 are under examination.¹ In response to the aforementioned Amendment, all rejections over prior art have been withdrawn. See Advisory Action dated Jan. 5, 2009. Claims 14, 19, 20, 25, 55, 56, 72, 75, 93-98 and 105-108 stand rejected under 35 U.S.C. §112, second paragraph for alleged indefiniteness. The rejection under section 112, second paragraph is the sole remaining rejection in the application.

II. STATEMENT OF APPLICANT'S POSITION

The strictures of section 112, second paragraph that Applicant particularly point out and distinctly claim the subject matter which he regards as his invention ensures the claims notify the public of activity that falls within the claims. The claims of the instant application are clear on their face. There is no evidence of record that one skilled in the art would not understand what is being claimed. Because the claims serve the notice function of section 112, second paragraph, the indefiniteness rejection should be withdrawn and the application passed to allowance.

The indefiniteness rejection should be withdrawn because the Examiner has committed the following clear errors.

¹ Claims 99-104 and 109-120 have been withdrawn from consideration by the Examiner as being directed to non-elected subject matter.

**III. THE EXAMINER FAILS TO APPLY THE PROPER STANDARD FOR INDEFINITENESS
UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

The standard for definiteness is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). The Examiner has failed to provide any supportable basis for concluding that one of ordinary skill in the art would not understand what is claimed when the claims are read in light of the specification.

Each of the pending claims is definite because when read in light of the specification, the skilled artisan “would understand what is claimed.” Claim 14, for example, reads as follows:

14. A method for inhibiting accumulation of amyloid β peptide in the brain of a patient suffering from Alzheimer’s disease, comprising contacting in vivo soluble amyloid β peptide in the cerebrospinal fluid of said patient with an exogenous free-end specific antibody which is targeted to a free N-terminus of amyloid β peptide or a free C-terminus of amyloid β peptide A β 1-40, to inhibit the accumulation of said amyloid β peptide in the brain of said subject patient.

Claim 14 is thus directed on its face to inhibiting accumulation of amyloid β peptide in the brain of a patient suffering from Alzheimer’s disease by contacting soluble amyloid β peptide in the CSF of the patient with a free-end specific antibody having the stated specificities. The step of contacting soluble A β in CSF antibody with exogenous free-end specific antibody is all that is required to carry out the claim’s stated purpose of inhibiting accumulation of A β in the brain. The claim is clear without any reference to a method by which antibody is provided to the CSF. The breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 693 (CCPA 1971). The metes and bounds of claim 14 are thus clear. Similarly, the metes and bounds of the other rejected claims are clear without reference to a method by which an antibody is provided to CSF (claims 19, 20, 25, 56, 55, 72 and 105-108) or, more generally, to a composition (claims 93-98).

Notwithstanding the clear language of the instant claims, the Examiner cites MPEP § 2172.01 and concludes the claims are indefinite “as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.” *See* Office Action dated September 13, 2006 and Final Office Action dated November 26, 2008. The Examiner’s reliance on section 2171.01 is misplaced and fails on both factual and legal grounds. First, it is factually incorrect to conclude that the claims lack an essential step. Claims 14, 19, 20, 25, 55, 56, 72, 75, and 105-108 are directed collectively to inhibiting accumulation or neurotoxicity of A β in the brain or reducing A β levels in the CSF of an Alzheimer’s disease patient. As set forth above, the step of

contacting soluble A β in the CSF of an Alzheimer's disease patient with free-end specific is all that is required to carry out the full scope of the respective methods. Accordingly, there is no factual basis to conclude that these claims lack an essential step. Claims 93-98 are drawn simply to obtaining an A β peptide-antibody complex. These claims recite the step of forming a composition essentially of an end-specific antibody, CSF and A β . The act of forming the composition leads directly to complex formation. In short, the respective single steps recited in the present claims lead to the respective stated purpose of each claim. There is thus no basis for concluding the claims lack an essential step. For at least this reason, the Examiner's reliance on section 2171.01 must fail.

Moreover, section 2172.01 states that claims are incomplete when omission of an essential step amounts "to a gap between the steps." The pending claims are directed to respective methods that each include a single step. Thus, it is factually incorrect (and logically not possible) for the claims to exhibit a "gap between the steps." For at least this reason, the Examiner's reliance on section 2172.01 must fail.

The Examiner's reliance on section 2172.01 also fails because the Examiner applies this section in a vacuum, without any showing that the claims fail to meet the legal standard for definiteness. The Board of Patent Appeals and Interferences has consistently recognized it is error to apply section 2172.01 (or corresponding predecessor sections 706.03(f) or 2173.05(1)) without otherwise providing evidence that one of ordinary skill in the art would not recognize the metes and bounds of the claims. In *Ex parte Nakano* (S/N 08/517,909 Appeal No. 98-0979) the Examiner asserted:

[The claims] are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps....One cannot perform the claimed invention since one cannot be certain of the steps required. In short, one must look to [the] patent specification and prosecution history since a doubt exists as to the scope of the claims. With such doubt one cannot clearly determine what the applicant regards as his invention.

Id. at page 8. The Board disagreed with the Examiner's analysis and overturned the rejection. The Board first noted that claim breadth is not to be equated with indefiniteness." (*citing Miller, supra*). The Board acknowledged that section 2172.01 states a claim is indefinite if it "fails to interrelate essential elements of the invention as defined by applicant(s) in the specification." *Id.* at 9. The Board, however, concluded:

[T]he Examiner has failed to cite any passage of the specification or in other statements of the record that would establish that any **essential** step has been omitted from the claims under appeal. The mere fact that other steps have been disclosed in the preferred em-

bodiment does not render each and every step thereof an **essential** step.

Id. (emphasis in original). In *Ex parte Kato*, S/N 08/455,366 Appeal No. 1998-2817 the Board found:

[T]he Examiner has failed to cite any passage of the specification or in other statements of record that would establish that any essential element or interrelationship between essential elements has been omitted from the claims under appeal. While the claims are certainly broader without a recitation of [the omitted limitation] than they would be if [the omitted limitation] were recited, that does not make the claims indefinite.

Id. at page 9. (affirmed on other grounds). Similar to Nakano and Kato, although the instant claims are broader without recitation of an administration step than they would be if an administration step were recited, the Examiner has failed to cite any passage of the specification or the record that indicates applicant considers administration to be an essential step of the claimed method.²

In *Ex parte Trummer* the Board recognized that “incompleteness rejection should be extremely rare” because “in almost every case...it could be said that every part of a disclosed combination is somehow essential to the overall purpose of the invention.” (S/N 08/127,924 Appeal No. 1997-1351 at pages 6-13 (internal quotations omitted; affirmed on other grounds). In short, the Board has consistently closely examined rejections predicated on “failure to recite an essential step,” and reversed rejections where the Examiner has failed to show that the Applicant has unambiguously disclosed an element as essential and that one of ordinary skill in the art would not understand the scope of the claims. Here, the Applicant has not disclosed an administration step as essential and the claims are clear on their face. The claims are not missing an essential step and the rejection should be withdrawn.

² For other Board decisions overturning rejections based on section 2172.01 or its predecessor sections see *Ex parte Kubota*, S/N 08/424,156 Appeal No. 2000-1241 at pages 5-6 (“[W]e find that the limitations which the examiner has challenged in the claims are broad rather than lacking in enablement or lacking in particularity.” (affirmed on other grounds); *Ex parte Cleaves*, S/N 08/581,347 Appeal No. 2003-1081 at page 3-4 (Portion of MPEP § 2172.01 “directed toward omitted essential subject matter pertains to nonenablement rejections under 35 U.S.C. § 112, first paragraph, not claim clarity rejections under 35 U.S.C. § 112, second paragraph. The portion of the relied-upon MPEP section directed toward claim clarity pertains to claims in which essential elements are recited but not interrelated, which is not the situation in the present case.”) (new ground of rejection under section 112, second paragraph set forth for indefiniteness of term “substantially”); *Ex parte Gallagher*, S/N 08/784,752 Appeal No. 2000-0909 at pages 4-7; *Ex parte Rothenberg*, S/N 09/006,982 Appeal No. 2002-0747 at pages 8-9; *Ex parte Cook*, S/N 09/107,688 Appeal No. 2002-0798 at pages 5-7; *Ex parte Stankov*, S/N 09/854, 802 Appeal No. 2007-3261 at page 10. cf *Ex parte Mehta*, S/N 08/595,150 Appeal No. 2000-0160 at page 3-7 (indefiniteness rejection affirmed for missing element that “Appellant in his brief insists is his invention” and without which the scope of the claims were unclear.)

IV. THE EXAMINER PREVENTS APPLICANT FROM CLAIMING AN ASPECT OF HIS INVENTION

The Examiner's assertion that without an administration step it is unclear how exogenous antibodies would be present *in vivo* is not well taken. Every aspect of a disclosed invention need not be present in the claims. *Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1182 (Fed. Cir. 1991). The Court stated:

It has long been held, and we today reaffirm, that it is entirely consistent with the claim definiteness requirement of the second paragraph of section 112, to present "subcombination" claims, drawn to only one aspect or combination of elements of an invention that has utility separate and apart from other aspects of the invention. [It] is not necessary that a claim recite each and every element needed for the practical utilization of the claimed subject matter, as it is entirely appropriate, and consistent with § 112, to present claims to only [one] aspect.

Id., citing *Bendix Corp. v. United States*, 600 F.2d 1364, 1369 (CCPA 1979). The Court concluded, "[T]he claimed device is capable of performing its claimed purpose...Greater utility or more definite claiming than this is simply not required." *Id.* Here, the respective claimed methods function apart from an administration step. The respective claimed methods are capable of performing their claimed methods. As set forth in *Carl Zeiss*, "more definite claiming is simply not required." *Id.* The Examiner has in essence found that the Applicant cannot claim part of his disclosed invention separate from the whole. "This reasoning is legal error." *Id.* For this additional reason, the indefiniteness rejection should be withdrawn.

V. CONCLUSION

One of ordinary skill in the art would understand what is claimed when the claims are read in light of the specification. The claims comply with the stricture set forth in section 112, second paragraph that the claims particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For at least the reasons set forth above, the Examiner has committed clear error in rejecting the claims under section 112, second paragraph and these rejections should be withdrawn.

Dated: February 19, 2009

Respectfully submitted,

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